Veeva & U Clinical User Community

March 07, 2019

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R&D Customer Success Manager

Veeva

Agenda

Thursday, March 7th	
15:00 – 15:15	Welcome & Announcements *Jenn Embury: Customer Success Manager, Veeva*
15:15 – 16:00	Sponsor Oversight of CROs *Jenn Embury: Customer Success Manager, Veeva*
16:00 – 16:45	Measuring and Monitoring Quality Using Reports and Dashboards *Anne Rudick- Lowe : Customer Success Manager, Veeva*
16:45 – 17:00	Questions & Answers *All*

Community Meeting Objectives

Foster *customer success* by …

Creating opportunities for customer interaction

Providing a forum to share practices

Promoting product education

Veeva R&D

SUMMIT

Europe

Unify & Connect | 11 – 13 June 2019 | Barcelona, Spain

400+ attendees from life sciences

90+ life science companies

Join our European R&D Community

Share Best Practices

Develop New Industry Partnerships

Network with Peers

REGISTER NOW

Clinical Operations

Regulatory

Quality

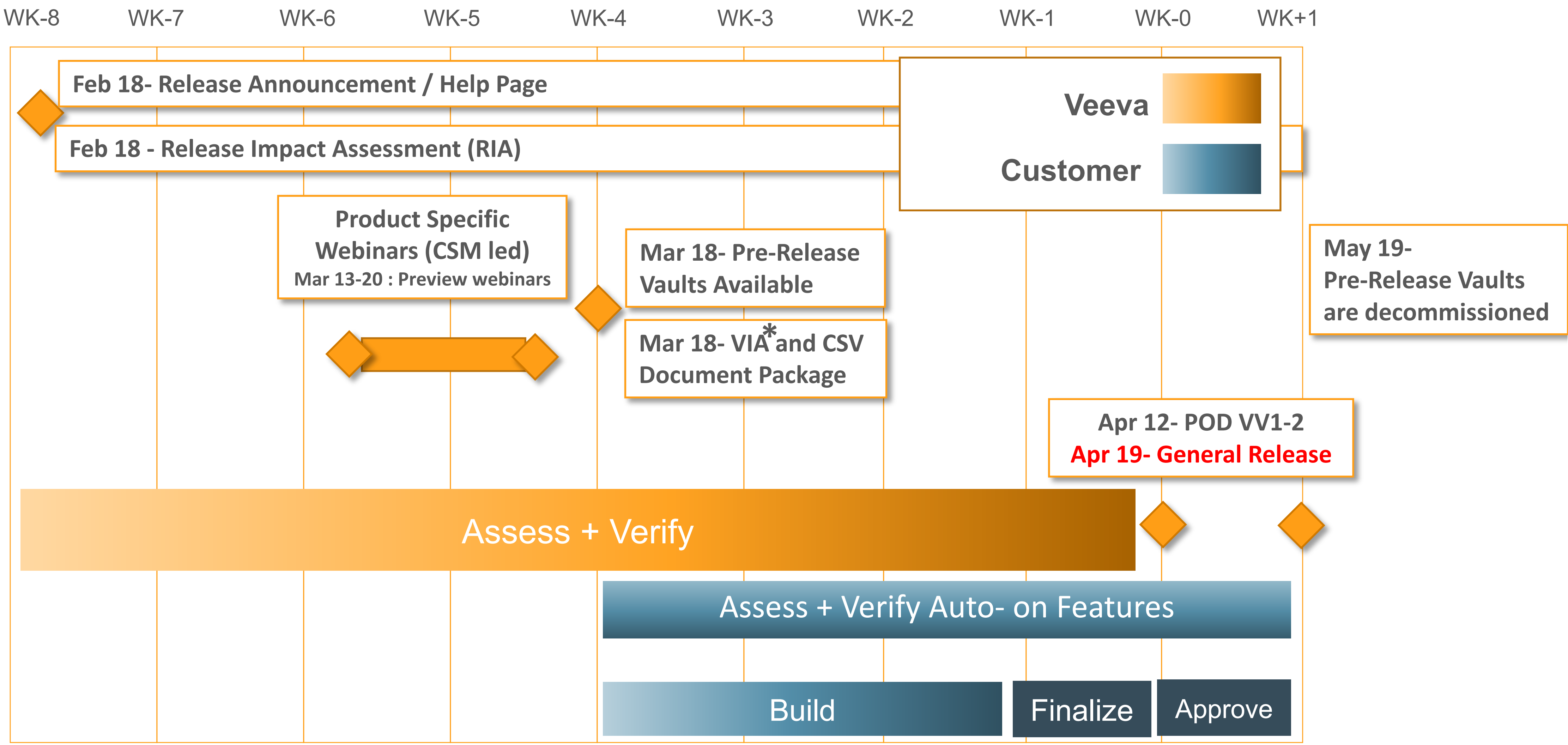
Vault Platform

Veeva & U

Vault Clinical User Meeting - Remote
7th March 2019
15:00 – 17:00 CET

Vault Clinical User Meeting at Summit (Onsite Only)
13th June 2019
13:15 – 15:00 CET

19R1 General Release (GR) Timing



* Validation Impact Assessment

Sponsor Oversight of CROs

EU Veeva & U Community Webinar

07 Mar 2019

Table of Contents

1	Sponsor Oversight - The Regulations
2	Sponsor Oversight of CROs- What does it mean?
3	Measuring and Monitoring Quality Using Reports and Dashboards

Regulations, Guidance, & Responsibility

FDA and ICH E6

- FDA
  - 21 CFR 312.52 Transfer of Obligations
    - Allows FDA to take regulatory action against contracted party when inspectional findings at the contracted site show failure to comply with regulations
    - Does not relieve sponsor of their regulatory responsibilities
    - Sponsors should evaluate CRO compliance (e.g. Sponsor periodic review of monitoring reports, vendor performance, quality metrics, documented communication)
- ICH E6
  - Section 5.2.1 – The Sponsor always remains ultimately responsible for the quality and integrity of a study
  - Section 5.2.2 – Sponsor oversight is not just limited to the vendors they contract, but also includes the vendor's third parties
- References:
  - FDA Guidance for Industry – Oversight of Clinical Investigations
  - 21 CFR 312.52
  - FDA Compliance Program Guidance Manual
  - ICH E6 (Section 5.2 Contract Research Organization)

FDA U.S. FOOD & DRUG ADMINISTRATION

European Medicines Agency (EMA)

- Guidance on the Content, Management, and Archiving of the Clinical Trial Master file, *published 06 December 2018, effective 06June 2019*
  - The sponsor may choose to outsource duties and functions of the sponsor to a CRO
  - The sponsor remains responsible for the trial and will need to maintain oversight. Therefore, access to the CRO maintained part of the sponsor TMF (e.g. by remote access to an eTMF) or at least regular access to relevant documents from it will be necessary to fulfil these responsibilities effectively

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-clinical-practice/gcp-inspectors-working-group

MHRA – Good Clinical Practice Guide

- 1.1.3 The sponsor can formally delegate one or more of the functions of sponsorship
- 1.3.1 Regardless of the model used, the sponsor retains ultimate responsibility for the clinical trial.
- 1.3.1 All vendors must show due diligence when performing any functions they have been delegated…
- 10.2.6 The role of the vendor in the trial would be expected to be formally documented in an agreement between the sponsor and the vendor, outlining the functions transferred to the vendor
- 10.2.6 One such plan that may be considered is a TMF plan, particularly when the interactions between a vendor and sponsor are quite involved and complex and the agreement would not provide a sufficient level of detail of the practical working relationship
- 10.2.6 This plan (where used) must be filed in the TMF

Medicines & Healthcare products
Regulatory Agency

Oversight

What does it mean?

CRO Oversight

- Is my CRO doing what I hired it to do?
- Are they adhering to the TMF Plan?
- Are they meeting or exceeding expectations?

CRO Oversight Activities & Documentation

Expectations

1. Vendor Assessment
2. Contracts and Agreements
3. Project Plans (including the TMF Plan)
4. Key Performance Indicators (KPIs)

Oversight

1. Project Meetings
2. Study Metrics Reviews
3. Co-Monitoring Visits
4. Sponsor TMF QC reviews

What is a TMF Plan?

- Describes the anticipated content of the Trial Master File (TMF)
- Is a living document that defines the process for creating, controlling, maintaining and archiving project-related document files

What is in your TMF Plan?

- TMF Index/doc types
- Responsible Departments
- RACI
- TMF procedures/setup
- User access
- TMF archival and retention process
- Inspection process
- Certified copy definition
- Quality KPIs
- Timeliness definitions

- https://tmfrefmodel.com/resources/

TMF Plan Template

Inspection Readiness RACI

Is my CRO doing what I hired it to do?

- No
  - Classifying incorrectly
  - Incomplete/wrong metadata
  - Uploading duplicate documents
  - Leaving documents unclassified in Inbox
- Yes
  - Providing high quality documents/few issues
  - Completing and uploading MVRs in alignment with monitoring plan
  - Contributing documents within xx days
  - Approving documents within xx days
  - Updating EDLs (if delegated)
  - Completing tasks on or before due date

Are they meeting or exceeding expectations?

- Apply a risk-based approach in the Sponsor’s QC process
- Leverage Vault reports and dashboards to measure KPIs
- Use the TMF Homepage to identify trends

Monitoring & Measuring Oversight

How Do We Demonstrate It?

Monitoring & Measuring Oversight

- Metrics
  - What are you measuring today?
- Interim Quality Reviews
  - When are you performing reviews and what's included?

Metrics: What to Measure?

- Quality Issue by Type
- Quantity of Documents
- Completeness
- Timeliness
- Comparing Sponsor to CRO Performance
- Comparing Multiple CROs
- Document Rejection Rate
- Upload Rate by Month by CRO
- Overdue Tasks, Workflows, and Document

Interim Quality Reviews: Timing

- By milestones
- As needed (e.g. when one record is returned)

DEMO

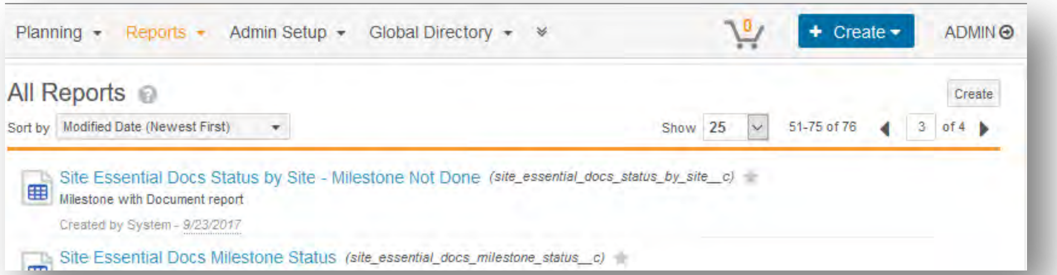
Questions

Building Your Own

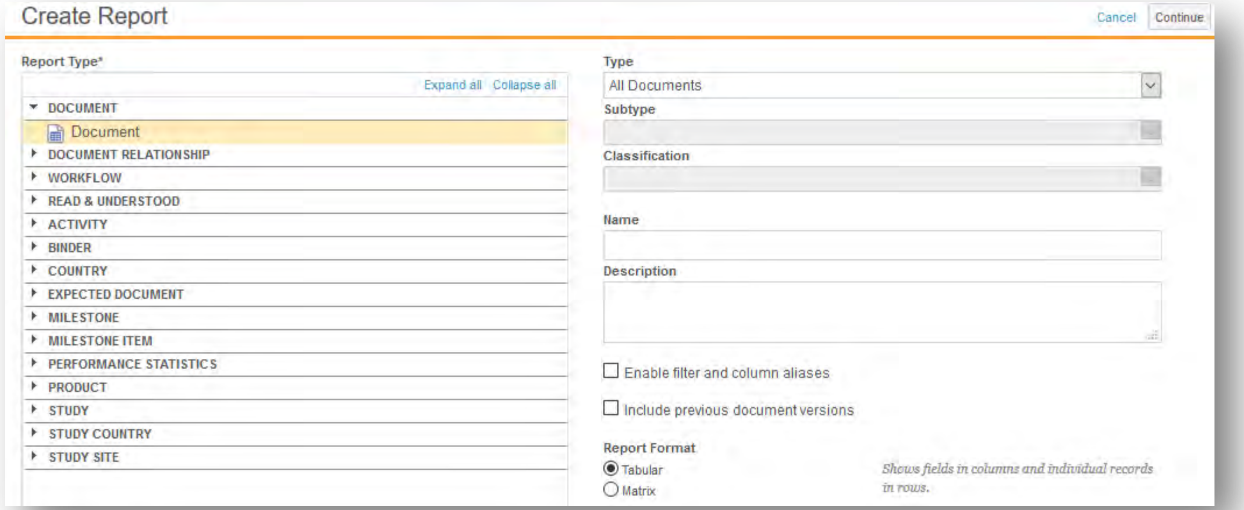
Quality Reports and Dashboards

Creating Reports

- To create a new Report, click the Create button on the Reports page

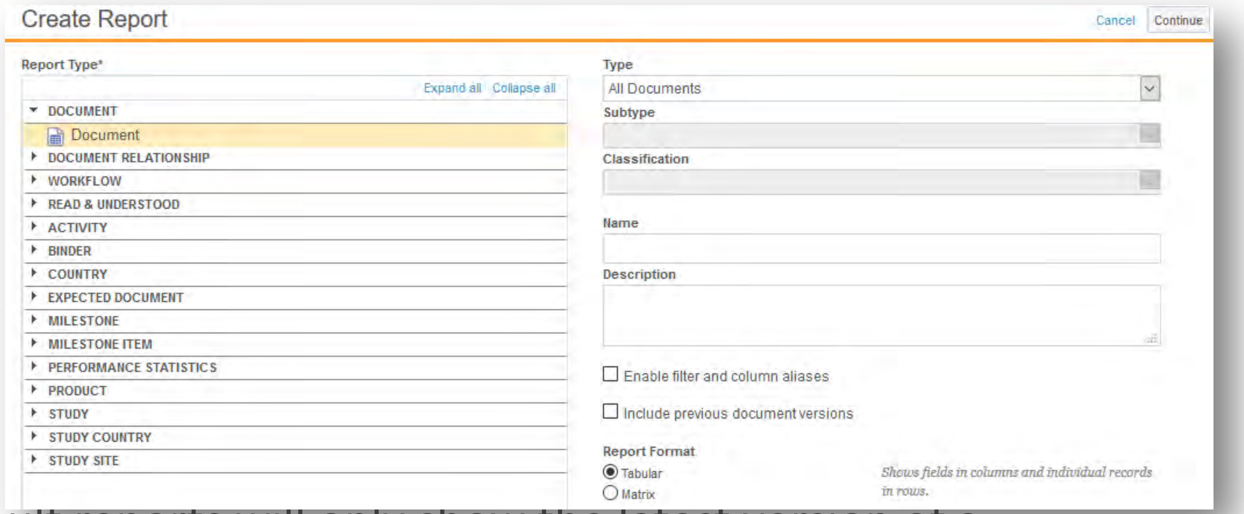


- When the Create Report screen opens, select the appropriate Report Type:



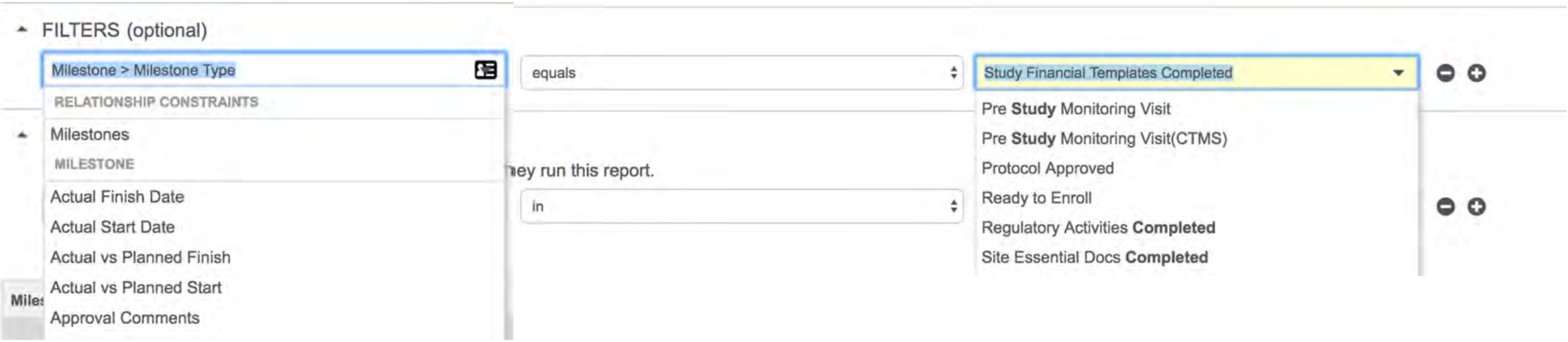
Creating Reports

- Enter a Report Name and Description
- Select a Report Format:
  - **Tabular** – Fields are displayed in columns and document records are displayed on each row
  - **Matrix** – Fields are displayed in both columns and rows allowing summary calculations to be performed
- Optional Filters:
  - **Type –** limits documents and fields shown to the type, subtype, and/or classification chosen
    - Document reports only
  - **Enable filter and column aliases** – allows for renaming columns and filters to be better understood by users
  - **Include previous document versions** – by default reports will only show the latest version of a document; this will show all versions
    - Document reports only



Creating Reports

- When the Report screen opens, specify any filters for the report by selecting appropriate properties, conditions and values



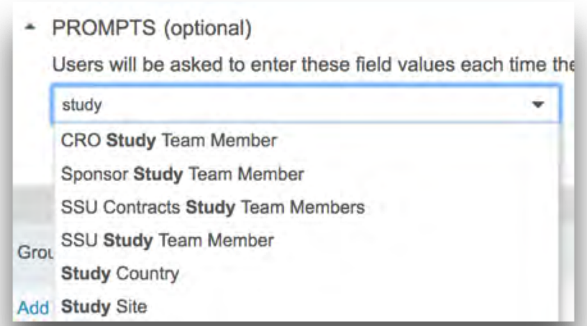
Creating Reports

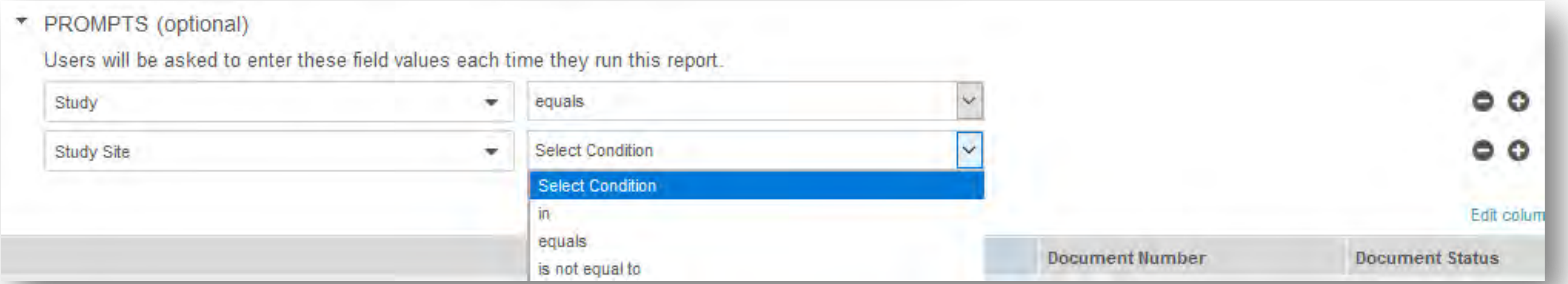
- Multiple filters can be applied by using the ⊕ button to add additional filters

- Clicking the ⊖ button can be used to remove an unnecessary filter

Creating Reports

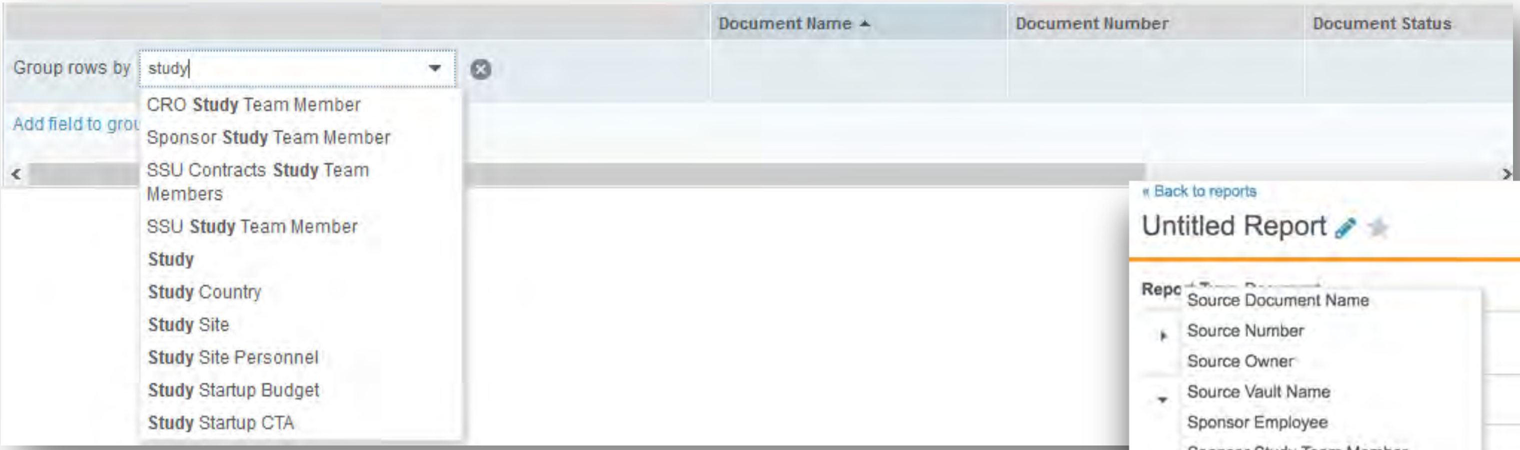
- If required, prompts can be added to further filter the report results by selecting the property and condition for the prompt
- A prompt appears as you run a report, requiring the user to enter certain filter criteria
  - Similar to filters, multiple prompts can be added (and subsequently removed) as needed

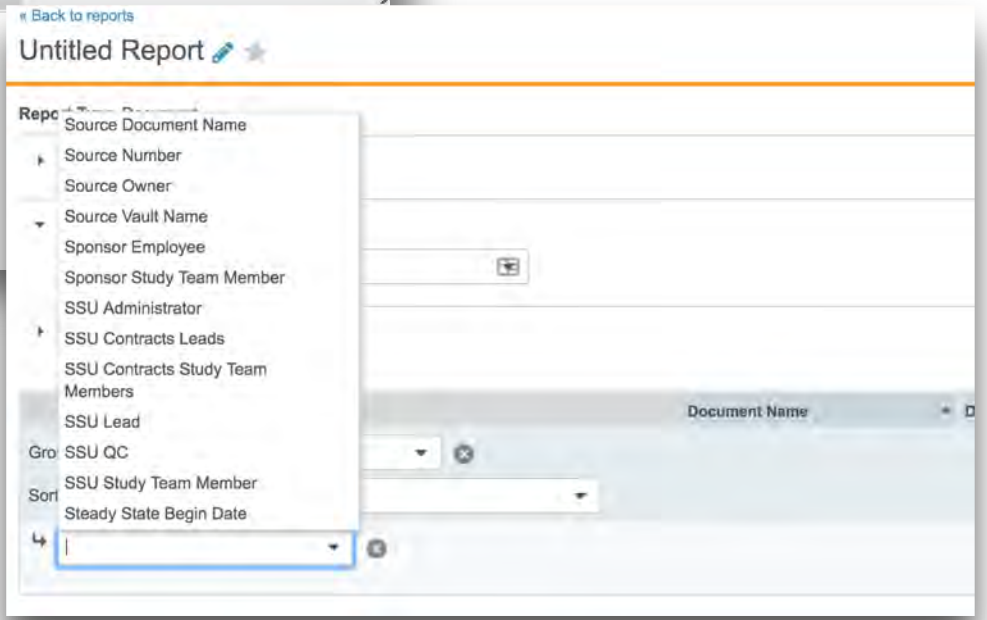




Creating Reports

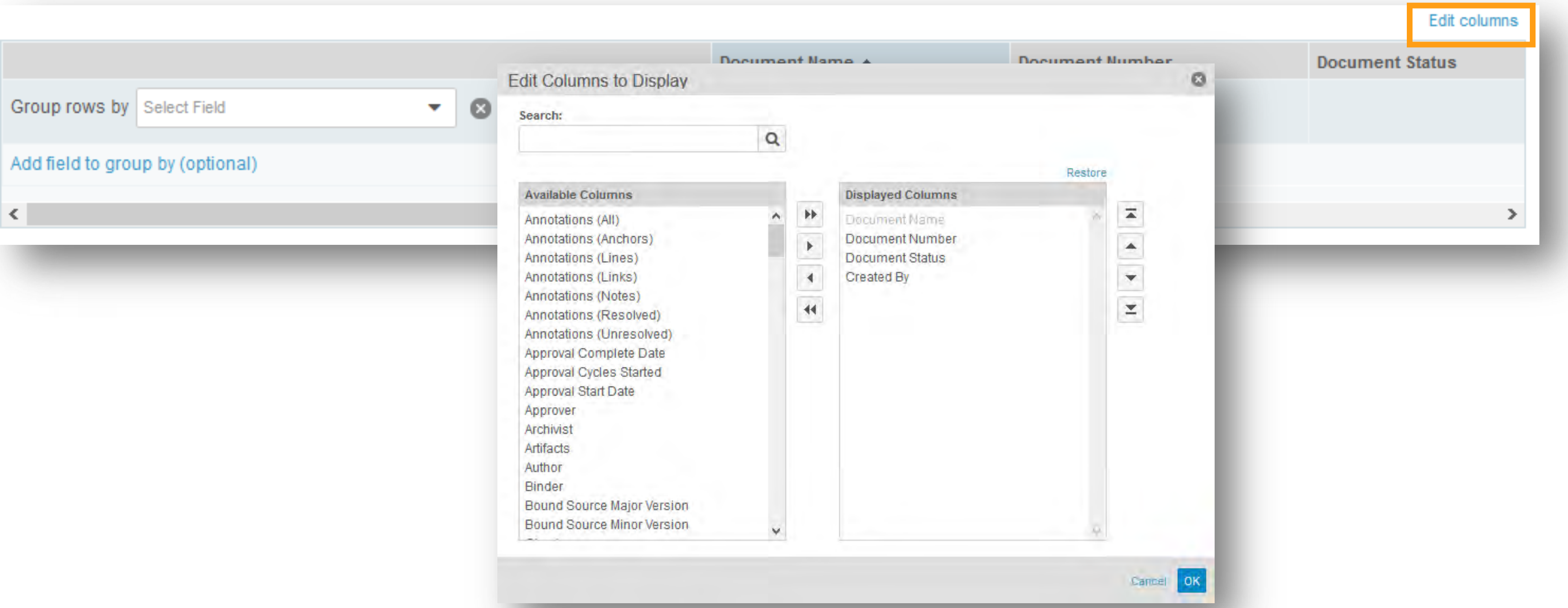
- Field groupings can also be applied to the report results
- Use groups to organize and sort your data by a specific field
  - A maximum of two grouping levels is currently permitted





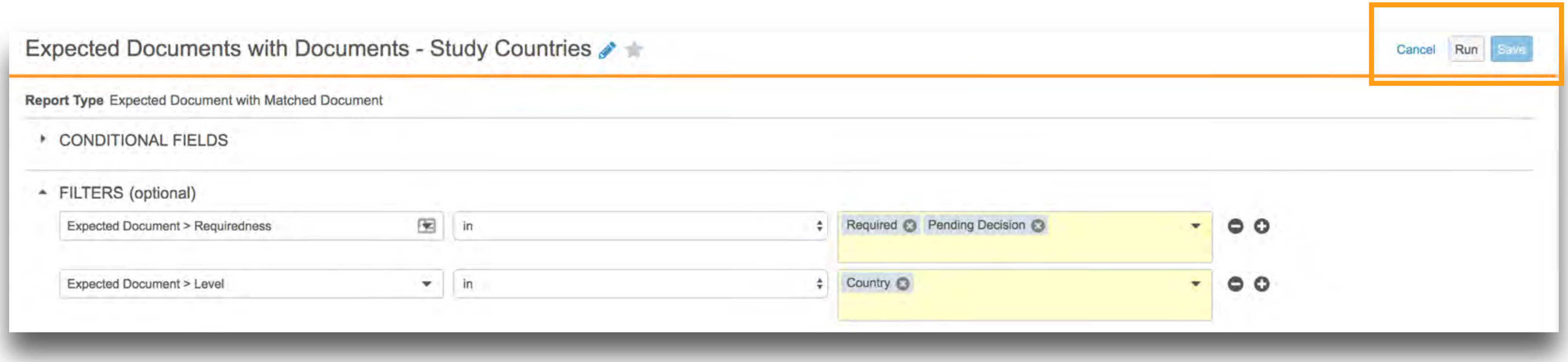
Creating Reports

- By clicking the Edit Column link, you can specify the columns to be displayed in the Report
- Select the columns from the Available Columns list and move them into the Displayed Columns list by clicking the right arrow to include them in the report
  - Columns in the Displayed Columns list can be reordered as needed by selecting a field and clicking the up or down arrows



Creating Reports

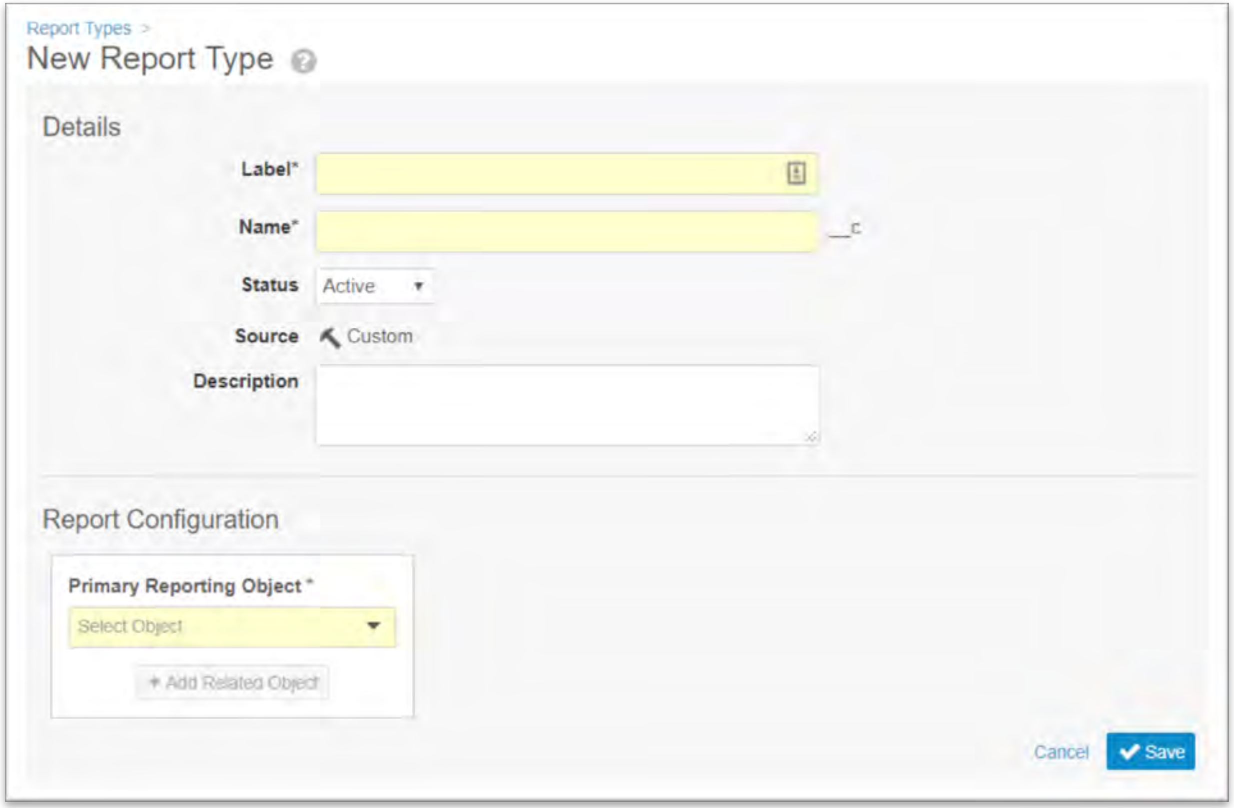
- Once the report filters, prompts, groupings and columns have been specified, you can perform the following actions
  - **Run**: Run will run the report without saving the specifics for future use
    - When the report is run, you have the options to continue editing, save or cancel the report. This is useful for testing the report as you configure it.
  - **Save**: Save will save the report so that it is available to be run in the future
  - **Cancel**: Cancel will return you to the Reports list without saving or running the report



Reports

Creating New Report Types

- If a report type isn't available, Admins can create new report types for existing objects
- Admin > Configuration > Report Setup > Report Types
- Select + Create
- Label the new Report Type
- Select the Reporting Objects



How to Create a Formula Field

- **Admin > Configuration > Document Fields**
  - Click on document type where you would like to define this formula field
- Click **Add…** and select **New Field**.
- Select **Formula** as the field type.
- Enter a label for the field. This label will appear when using the field as a report column, filter, or group by field.
- Set the **Status**. If *Active*, the field will be available as soon as you save. If *Inactive*, you’ll have to change the status before the field is available.
- Choose the number of **Decimal Places** that Vault should round to for the field’s final value.

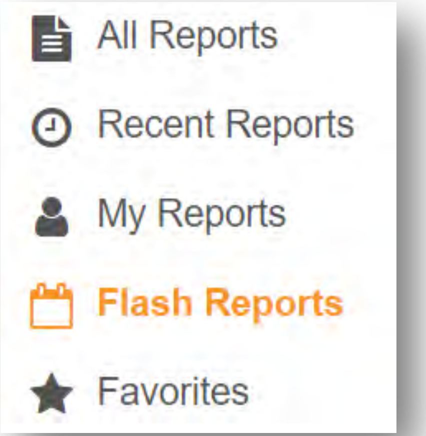
How to Create a Formula Field

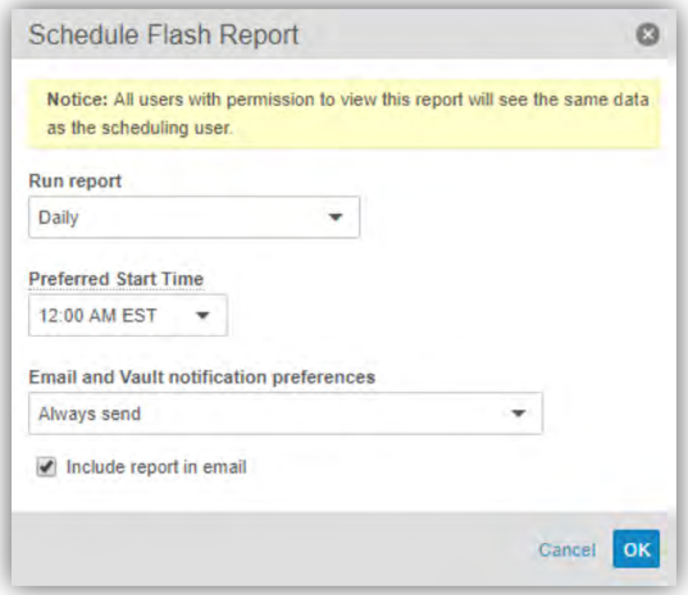
- Use items from the **Fields** and **Functions** panels, plus math operators as needed, to create an expression in the **Formula** field. To move an item from these panels to the **Formula** field, highlight it and click the arrow icon. The **Formula** field functions like a basic text editor. Learn more about available functions and operators in the Vault Formula Reference Guide.
- Click **Validate**. Vault will let you know if your expression is valid.
- Choose a **Field Value Handling** option. **Treat blank values as zeros** allows Vault to perform calculations even if one or more values is blank. **Treat blank values as blanks** returns a null or invalid result if the formula contains blank values. Learn more about Blank Value Handling.
- Optional: Enter text for **Help Content**. This text appears when a user hovers over the document field name.
- Click **Save**.

Reports

Flash Reports

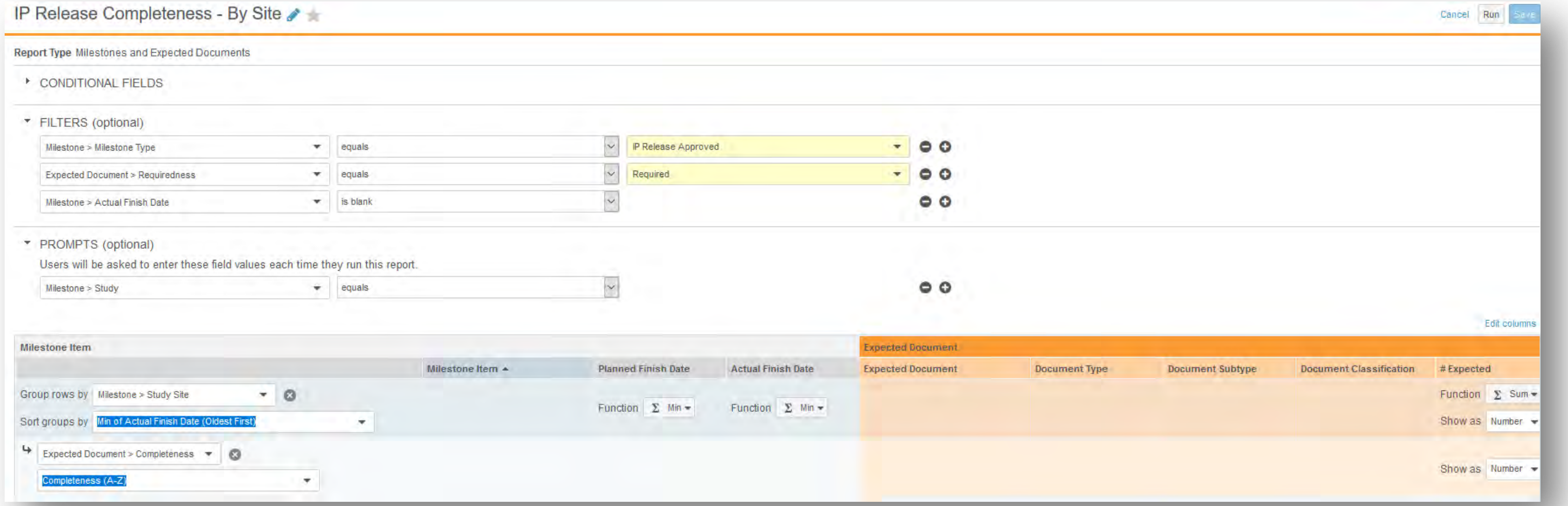
- Schedule reports on a daily, weekly, or monthly frequency
  - Can distribute via email to users with the Editor or Viewer role
  - Recipients receive a link with instant access to the most recent cached report results in Vault without needing to rerun the report
  - A preview of the report can be included in the Flash Report email
  - **Recipients do not require view permissions on underlying object records or documents to view the cached flash report results**
  - Cannot be refreshed
  - Not available for reports with prompts





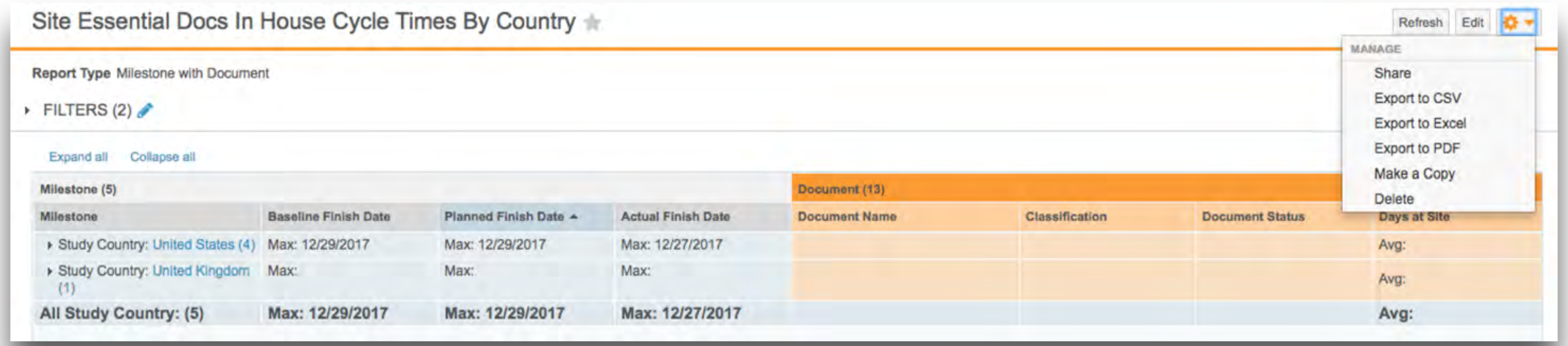
Editing Reports

- When you select to edit the report, the filters, grouping and prompts previously specified will be displayed and available for modification



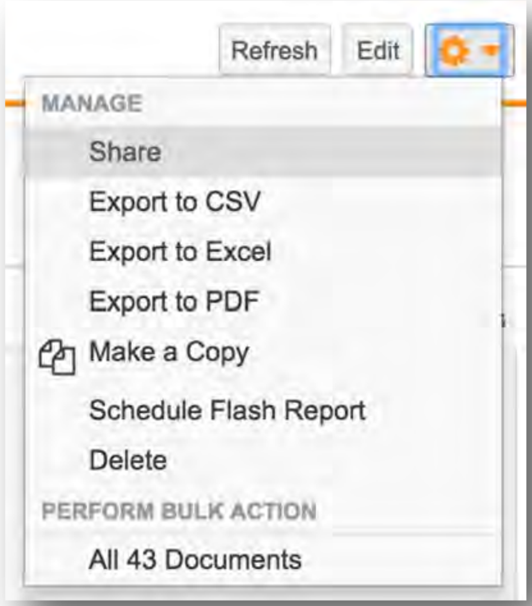
Editing Reports

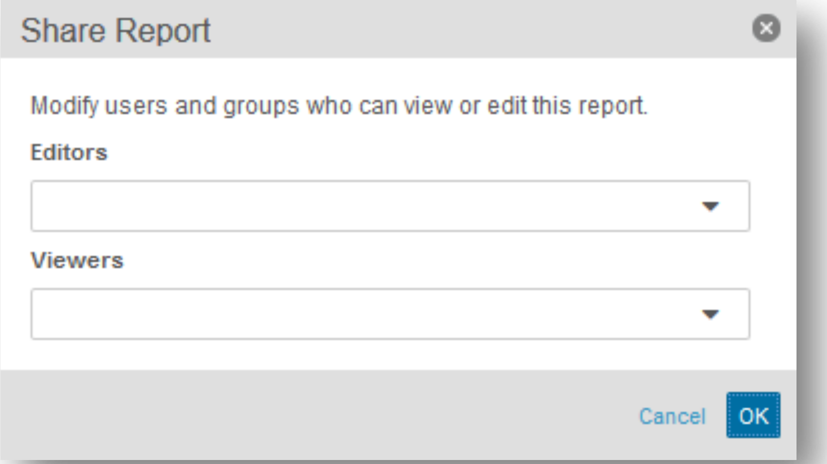
- After saving the report, you will be able to run it, edit it and perform other actions
- When the report is run, the real-time results will be displayed with the options to
  - **Refresh**: Rerun the report with updated results
  - **Edit**: Make modifications to the filters, prompts, and groups of the report
  - From the Actions Menu, you have the options to:
    - Share the report with other users
    - Export the report results to CSV, Excel, or PDF
    - Make a copy of the report
    - Delete the Report



Sharing Reports

- A report is only accessible to the user who creates it unless they choose to Share it
- When a report is shared, the creator can specify users who can edit the report as well as users who can view the report

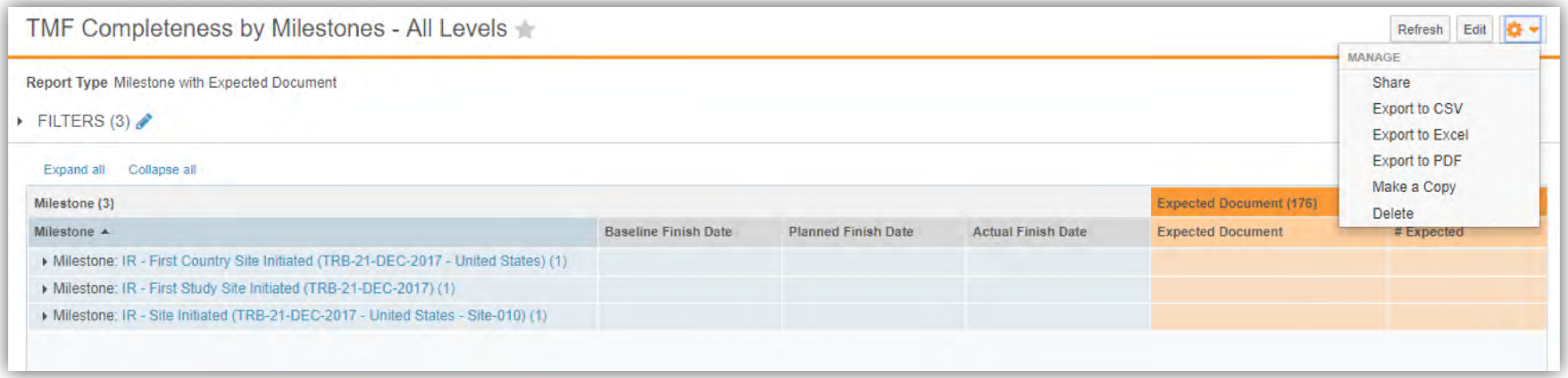




Reports

Exporting Reports

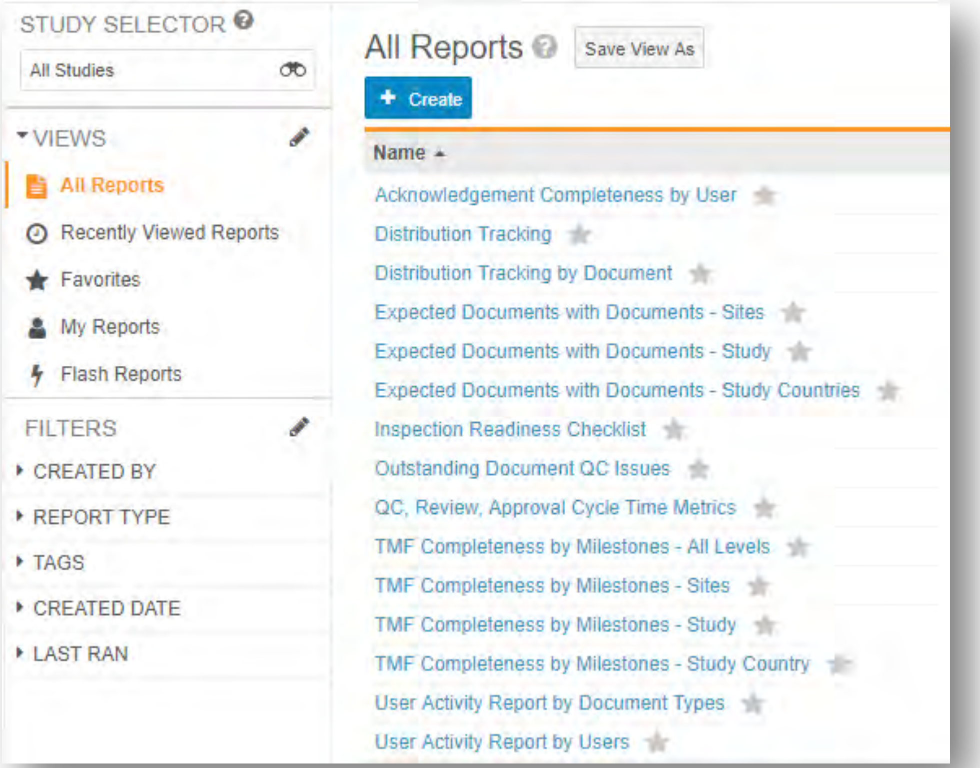
- Reports can be exported as CSV, Excel, or PDF



Reports

Views and Favorites

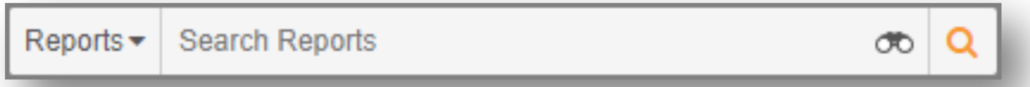
- From the **Reports** tab, you'll see several views:
  - **All Reports** shows all reports in the vault for which you are an Owner, Viewer, or Editor. All other views are subsets of this view.
  - **Recent Reports** shows the last 20 reports that you have viewed, edited, or created.
  - **My Reports** shows only reports that you have created.
  - **Favorites** shows reports that you have marked as a favorite by clicking the star icon.
  - **Flash Reports** shows all flash reports in the vault for which you are an Owner, Viewer, or Editor
- From the **All Reports** view, you can also use search and filters and edit the column layout to create custom views.
- Click **Save View As** to save this view to your **Views** panel.

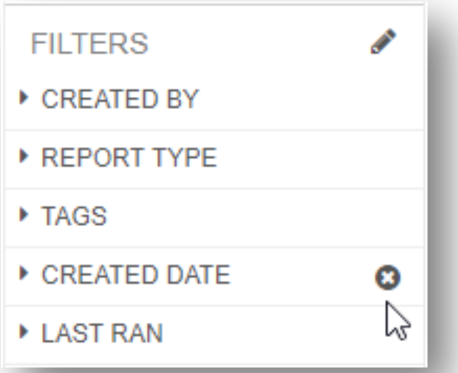


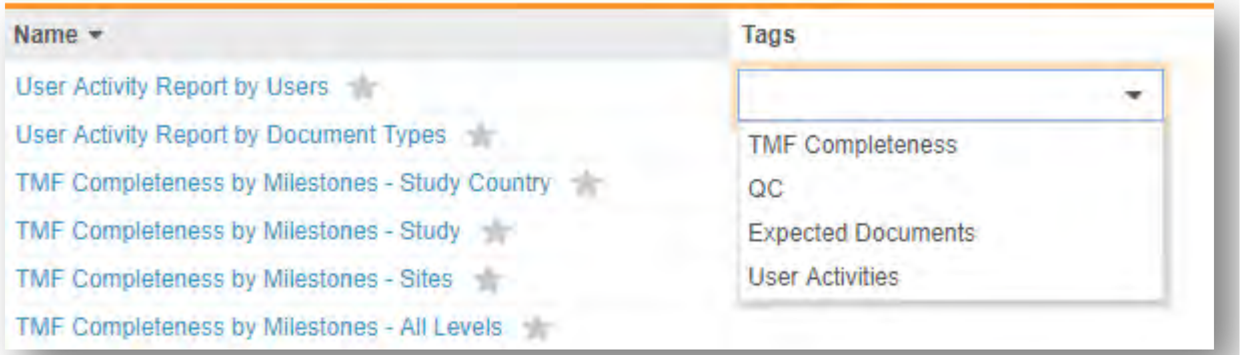
Reports

Searching, Filtering and Tagging

- Search
  - Select *Reports* in the main search bar
  - Vault searches within the report’s name, report type, description, and fields
  - Results are displayed in a filtered view in the **Reports** tab
- Filters
  - Use the **Filters** option to refine the list of displayed reports in any view or within search results
  - Applied filters can be removed by hovering over the filter and clicking the
- Tags
  - Tags can be assigned to a report to make it easier to group, search and filter your reports
  - To add tags, click into the **Tags** field for a report and select a tag from the picklist
  - The tags picklist is configured by your Admin





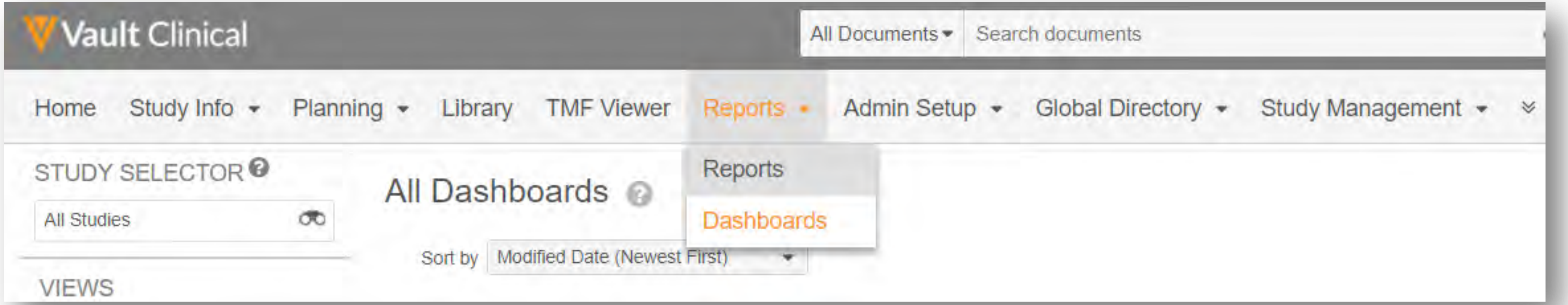


Dashboards

Dashboards

Overview

- Dashboards are located through the Reports tab



- Dashboards are visual representations of reports – must have a report before you can create a dashboard
- Can put multiple chart types on a dashboard
  - Gauge
  - Number
  - Column
  - Bar
  - Pie

Resource: http://vaulthelp2.vod309.com/wordpress/user-help/reporting-user-help/using-dashboards/

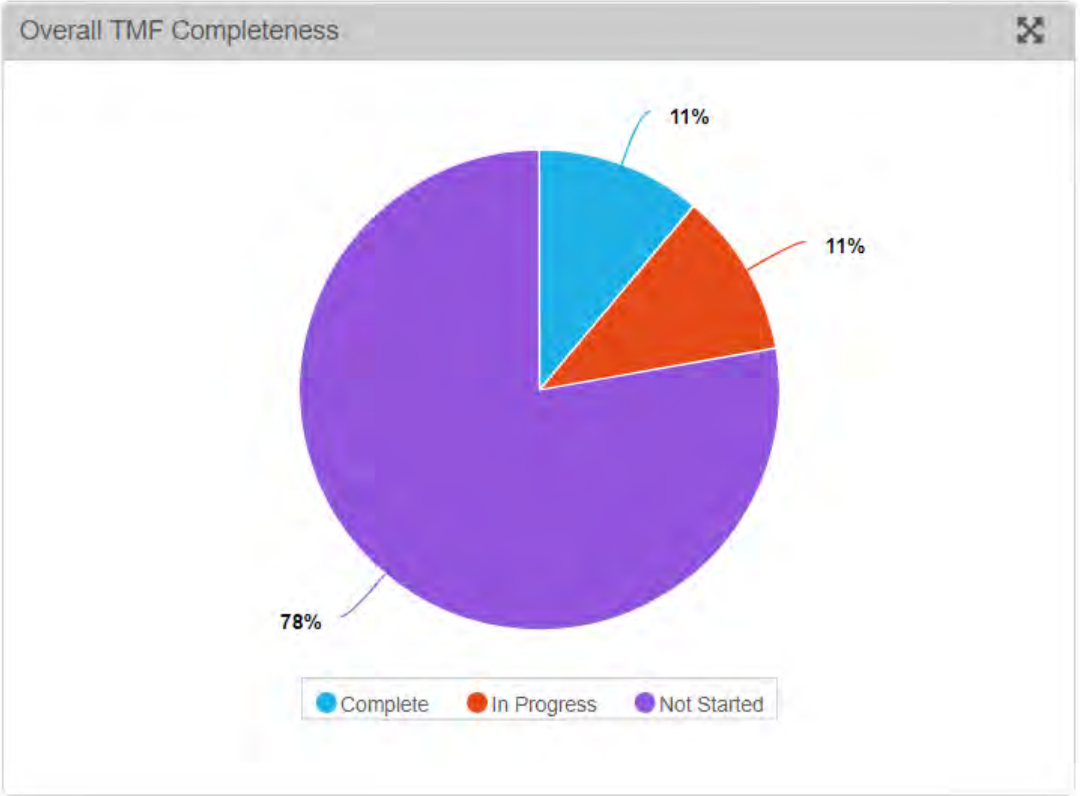
Dashboards

TMF: Content Processing Metrics

- Average days of documents in the Review workflow until completion
- Average days of documents in the QC workflow until completion
- Average days of documents in the Approval workflow until completion

Dashboards

TMF Completeness

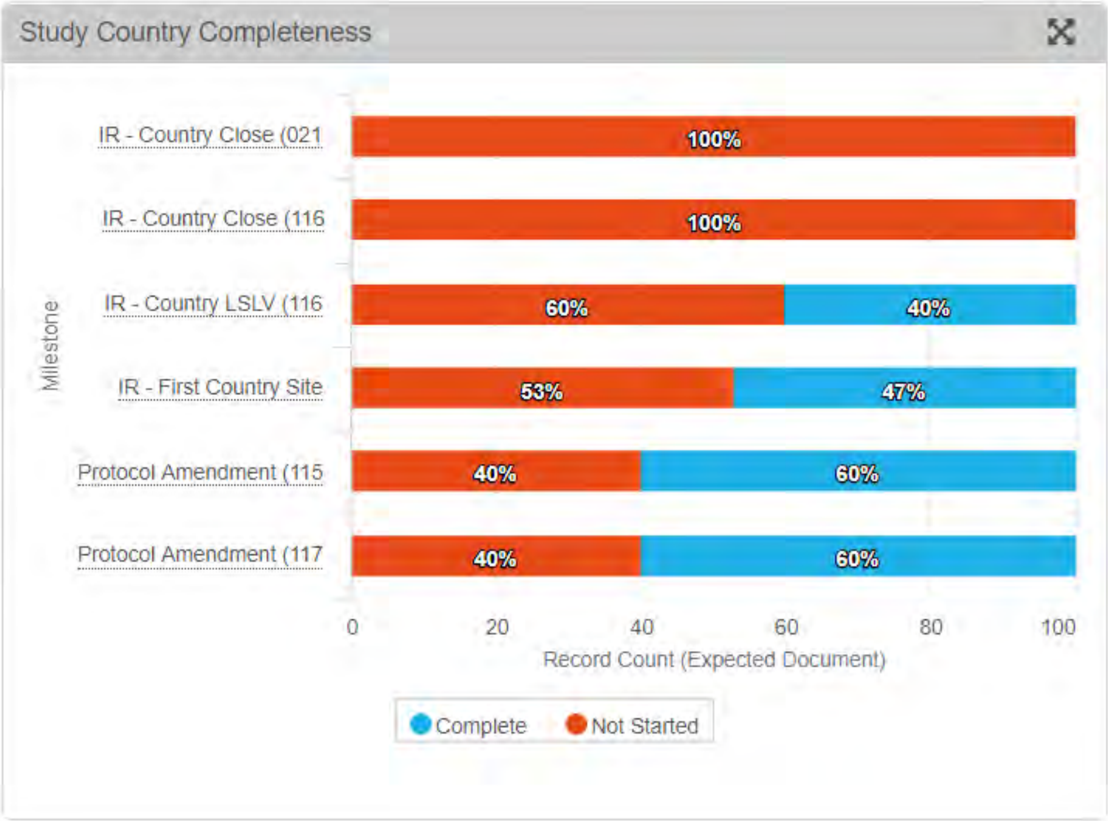


% of document completeness at all levels for the Study selected, categorized by the completeness status

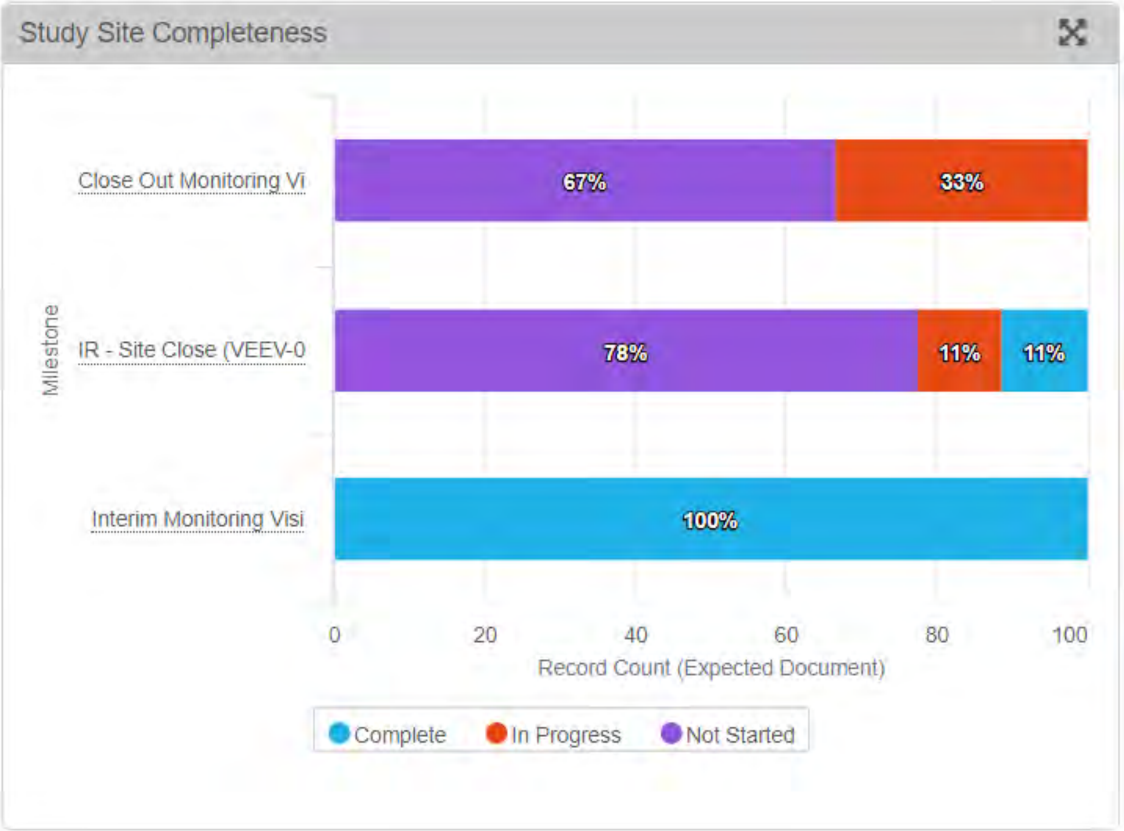
% of document completeness at the Study level for the Study selected, categorized by the completeness status

Dashboards

TMF Completeness



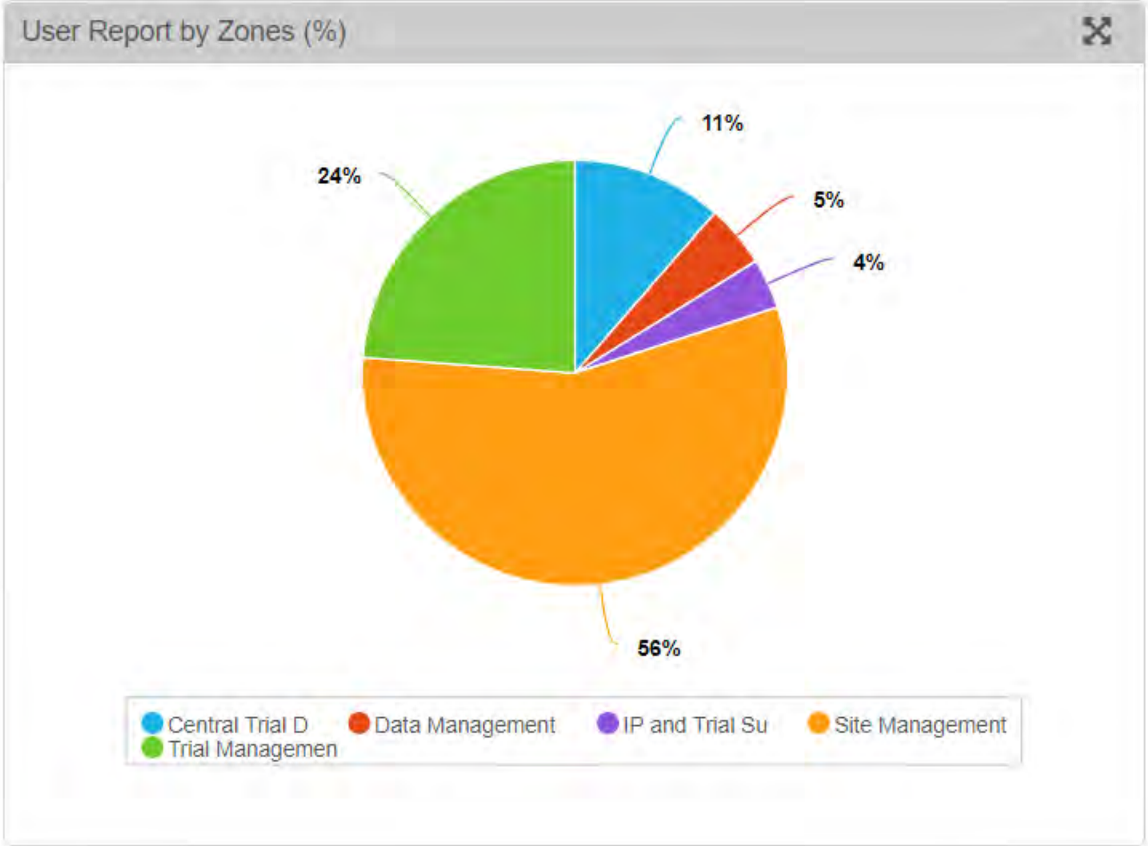
% of document completeness at the Study Country level for the Study selected, categorized by the completeness status



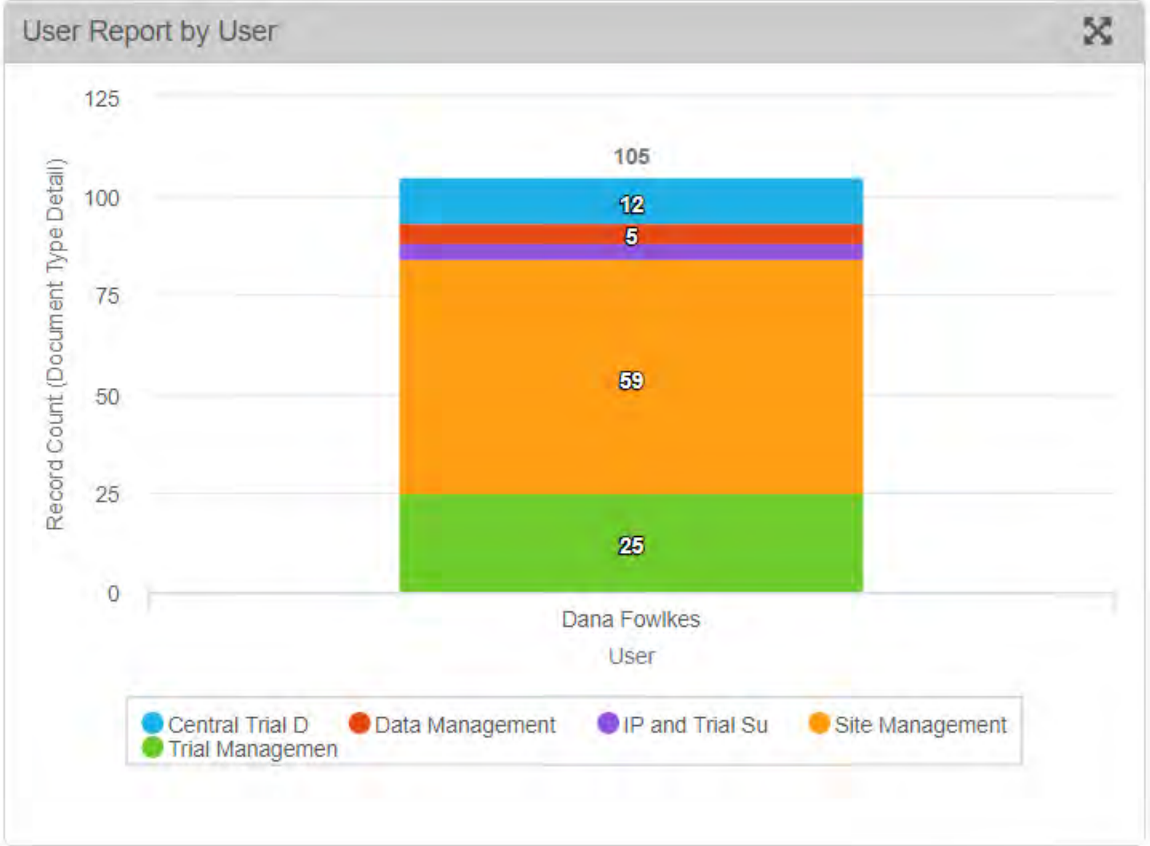
% of document completeness at the Study Site level for the Study selected, categorized by the completeness status

Dashboards

TMF: User Activities



% of document types accessed categorized by zones



# of document types accessed categorized by zones

Tips & Tricks

Best Practices for Reports

- Reports will continue to be refined as your processes and use of the Vault application evolve
- Use controlled values for columns
  - Free text fields are less effective
- Ensure Reports provide Value
  - Should assist the user in finding answers, not an extra burden to hunt for the data
- Consider metrics which have already been defined
- Think about what other users will find important about documents and their statuses
- Think about useful reports and trackers that you currently have or would like to have

Dashboard Tips

- Use stacked bar/columns for multi-level grouping
- Add target values in chart to compare to goals
- Export chart images to include in PowerPoint
- Use run-time input to create one dashboard that can be used under different context

Resources

- Vault Help
- Report Basics Video Tutorial
- Building Tabular Reports Video Tutorial
- Building Matrix Reports Video Tutorial
- Building Dashboards

Questions

Thank you

Appendix

TMF Plan Template

Microsoft
Word Document